The Claim Amendments.

The Office Action states that Claims 1-7 and 9 are generic to a plurality of disclosed patently distinct species comprising "neutral receptor binding agent," "opioid antagonist analgesic," and "a partial mu-opioid agonist." The Applicant wonders if the Office Action has a typographical error in it, as the claims at issue claim an "opioid agonist analgesic, rather than an "opioid antagonist analgesic." The invention is intended to claim a pharmaceutical comprising an opioid agonist (analgesic) and either a neutral receptor binding agent or a partial mu-opioid agonist.

In light of the above, the Applicant takes the Office Action to mean that a election/restriction is required as to whether a "neutral receptor binding agent" is elected to be combined with an opioid agonist, or whether a "partial mu-opioid agonist" is elected to be combined with an opioid agonist. The Applicant elects the latter, a partial mu-opioid agonist."

If a species of opioid agonist and of partial-mu opioid agonist are required to further the patent application, the Applicant would elect noroxycodone as the opioid agonist, and nalbuphine as the partial-mu opioid agonist.

The Applicant reserves the right to re-claim a "neutral receptor binding agent" in any subsequent patent application to this 10/628,089 application, whether it be a divisional, continuation, continuation-in-part, or other such application claiming this application for a priority date of July 25, 2003.

In light of the foregoing, the Applicant herein amends the claims as stated starting on a separate paper enclosed herewith and titled "Amended Claims." These claim amendments are preliminary to any official action on the merits of the claims, and

are regarded as a Preliminary Amendment under 37 C.F.R. §§ 1.115 and 1.104.

In the Claims

Claims 1, 3, 6, 8, 10, 12 are cancelled as directed to the non-elected neutral receptor binding agents. Claims 2, 4, 7, 9, 11, and 13 are amended to correct errors of form. Claim 5 is as previously presented. New Claims 14-23 are added as preliminary amendments.

The opioid agonists of Claims 9, 11, and 13 are referenced at pages 68-69 of the Specification. The non-opioid analgesic acetaminophen claimed in Claim 17 is found at line 22 of page 65 of the Specification, and at lines 8-11 on page 66 of the Specification. The NSAID's claimed in Claims 18 and 19 are found at lines 20-24 on page 68 and lines 1-3 on page 69 of the Specification. The COX-2 inhibitors claimed in Claims 20-21 are described at lines 20-24 on page 69 and lines 1-5 on page 70 of the Specification. The α3β4-nicotinic receptor antagonist claimed in Claim 22 is referenced at lines 11-13 on page 70 of the Specification. The dose ratios of nalbuphine to hydrocodone claimed in Claim 23 is found at lines 19-24 on page 48 and at line 1 on page 49 of the Specification.

This leaves three independent claims pending, and 17 claims total. Therefore, no additional fees are due.

Typographical Error

The Applicant also wishes at this time to correct a typographical error on page 70 of the Specification. In the second full paragraph on page 70, at line 13, the co-pending U.S. patent application is mistakenly stated as "10/127,358;" the correct U.S. patent application number is 10/127,359.

* * * *

Pursuant to MPEP § 502.03 and 35 U.S.C. 122, the Applicant hereby provides the following written authorization for the Examiner or the U.S.P.T.O. to contact the Applicant by e-mail:

Recognizing that Internet communications may not be secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file.

Applicant may be reached at:

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* * * *

An early and favorable Office Action is respectfully solicited.

Sincerely submitted,

BY _____
David L. Simon, M.D., Pro Se Applicant
Mansfield Center, CT U.S.A.

AMENDED CLAIMS

I claim by letters patent:

Claims 1, 3, 6, 8, 10, 12 are cancelled.

Claim 2 (currently amended). A ~~combination~~ pharmaceutical ~~preparation~~ comprising: an opioid agonist analgesic;

a partial mu-opioid agonist;

and, an acceptable pharmaceutical carrier thereof.

Claim 4 (currently amended). The ~~invention~~ pharmaceutical of Claim 2 wherein said partial mu-opioid agonist is nalbuphine.

Claim 5 (previously presented). An opioid agonist analgesic comprising noroxycodone and a suitable pharmacological carrier thereof.

Claim 7 (currently amended). A ~~combination~~ pharmaceutical ~~preparation~~ comprising: an opioid agonist analgesic;

xorphanol;

and, an acceptable pharmaceutical carrier thereof.

Claim 9 (currently amended). The invention of Claim 2 wherein said opioid agonist analgesic is ~~any one~~ selected from the group consisting of:

alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphone, butorphanol, clonitazene, codeine, desmorphine, dextromoramide, dezocine, diampromide, diamorphone, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, levophenacylmorphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metopon, morphine, myrophine, narceine, nicomorphine, norlevorphanol, normethadone, noroxycodone, nalorphine, nalbuphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phemorphan, phenazocine, phenoperidine, piminodine, piritramide, propheptazine, promedol, properidine, propoxyphene, sufentanil, tilidine , ~~and~~ tramadol , and their respective acids, bases, salts, and stereoisomers.

Claim 11 (currently amended). The ~~invention~~ pharmaceutical of Claim 4 wherein said opioid analgesic is ~~any one~~ selected from the group consisting of:

alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphone, butorphanol, clonitazene, codeine, desmorphine, dextromoramide, dezocine, diampromide, diamorphone, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, levophenacylmorphan, lofentanil, meperidine, meptazinol, metazocine,

methadone, metopon, morphine, myrophine, narceine, nicomorphine, norlevorphanol, normethadone, noroxycodone, nalorphine, ~~nalbuphine,~~ normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phemorphan, phenazocine, phenoperidine, piminodine, piritramide, propheptazine, promedol, properidine, propoxyphene, sufentanil, tilidine , ~~and~~ tramadol , and their respective acids, bases, salts, and stereoisomers.

Claim 13 (currently amended). The ~~invention~~ pharmaceutical of Claim 7 wherein said opioid analgesic is ~~any one~~ selected from the group consisting of:

alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphone, butorphanol, clonitazene, codeine, desmorphine, dextromoramide, dezocine, diampromide, diamorphone, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, levophenacylmorphan, lofentanil, meperidine, meptazinol, metazocine, methadone, metopon, morphine, myrophine, narceine, nicomorphine, norlevorphanol, normethadone, noroxycodone, nalorphine, nalbuphine, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phemorphan, phenazocine, phenoperidine, piminodine, piritramide, propheptazine, promedol, properidine, propoxyphene, sufentanil, tilidine , ~~and~~ tramadol , and their respective acids, bases, salts, and stereoisomers.

Claim 14 (new). The pharmaceutical of Claim 2 wherein the opioid agonist analgesic and the partial mu-opioid agonist are not one and the same.

Claim 15 (new). The pharmaceutical of Claim 9 wherein the opioid agonist analgesic and the partial mu-opioid agonist are not one and the same.

Claim 16 (new). The pharmaceutical of Claim 2 wherein said pharmaceutical further comprises a non-opioid analgesic.

Claim 17 (new). The pharmaceutical of Claim 16 wherein said non-opioid analgesic is acetaminophen.

Claim 18 (new). The pharmaceutical of Claim 16 wherein the non-opioid analgesic is a non-steroidal anti-inflammatory drug (NSAID).

Claim 19 (new). The pharmaceutical of Claim 18 wherein the non-steroidal anti-inflammatory drug is selected from the group consisting of:

ibuprofen, diclofenac, naproxen, benoxaprofen, flurbiprofen, fenoprofen, flubufen, ketoprofen, indoprofen, piroprofen, carprofen, oxaprozin, pramoprofen, muroprofen, trioxaprofen, suprofen, aminoprofen, tiaprofenic acid, fluprofen, bucloxic acid, indomethacin, sulindac, tolmentin, zomepirac, tiopinac, zido-metacin, acemetacin, fentiazac, clidanac, oxpinac, mefenamic acid, meclofenamic acid, flufenamic acid, niflumic acid, tolfenamic acid, diflurisal, flufenisal, piroxicam, sudoxicam, and isoxicam.

Claim 20 (new). The pharmaceutical of Claim 16 wherein the non-opioid analgesic is a COX-2 inhibitor.

Claim 21 (new). The pharmaceutical of Claim 20 wherein the COX-2 inhibitor is selected from the group consisting of:

celecoxib (SC-58635), DUP-697, flosulide (CGP-28238), meloxicam, 6-methoxy-2-naphthylacetic acid (6-MNA), MK-966, nabumetone, nimesulide, NS-398, SC-5766, SC-58215, and T-614.

Claim 22 (new). The pharmaceutical of Claim 2 wherein said pharmaceutical further comprises an α3β4-nicotinic receptor antagonist.

Claim 23 (new). The pharmaceutical of Claim 11 wherein the ratio of nalbuphine to hydrocodone ranges from approximately 0.1:10 to approximately 0.2:10.